ResMed product servicing requirements

Training plan
May 2013

Scope
These requirements apply to all service centres which service and rework ResMed products, including ResMed service centres, external distributors and sub-contractors.

Work environment

Contamination controls

It is ResMed policy to promote a clean and tidy work environment. It is imperative to keep service areas clean, dry and free from accumulate waste, dirt, and debris. The following is required of the service environment:

- ☐ An area should be designated for the cleaning of returned units. This area should be wiped down with a lint free cloth and a cleaning agent with a high alcohol content (e.g. isopropyl alcohol) once a day or as required

⚠ **Warning – When using a cleaning agent with a high alcohol content refer to the appropriate Material Safety Data Sheet (MSDS) to ensure safe handling of the cleaning agent.**

- ☐ Work stations are to be kept as clean and clear as possible, and wiped down with a cleaning agent with a high alcohol content, as required
- ☐ The floor is to be kept clear of rubbish and other items at all times.
- ☐ Service technicians are to ensure that they maintain a high level of personal hygiene. Use of highly scented/antiseptic cleaners should be avoided.
- ☐ For personal protection and to ensure product quality, jewellery and other items that could damage products must be removed or otherwise prevented from coming into contact with products.

Units returned for service or repair

Before the servicing or repair activity commences, all units returned for repair are to be cleaned. This will ensure units are clean, thus reducing the risk of contamination and cross infection.

- ☐ Upon receipt of a unit, it should be taken to the designated cleaning area.
- ☐ The unit should be wiped down with a lint free cloth and a cleaning agent with a high alcohol content (e.g. isopropyl alcohol).
- ☐ The device should then be clearly identified as having been cleaned.

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Environmental controls

Environmental controls are required to ensure product quality and testing accuracy when servicing and storing ResMed products and parts. Temperature and humidity limits for ResMed devices are shown in the table below:

	Parameter	***Recommended value***
☐	Temperature	10 – 35 °C
☐	Humidity	15 – 95 % RH

Note: These limits must be adjusted by the service centre to comply with any test or measuring equipment used that is not already specified to operate to or beyond these limits.

Static precautions

Work station

☐ Work benches where handling and repairs are done must have surfaces of suitable conducting material connected via a 1 MΩ resistor to an electrical ground.

☐ The area under and also in front of the work bench must be coated with a suitable conductive floor paint, or alternatively, covered with a conductive floor mat. The conductive paint coating or floor mat must be connected to an electrical ground.

Soldering irons and equipment

☐ Soldering irons or solder baths must be at the same reference (ground) potential as the work bench.

Personnel

☐ A wrist strap must be worn by service personnel working at the bench. The wrist strap must have a conductive lead (1 MΩ connected to the bench surface. Alternatively, a heel ground strap to ground the operator to the floor may be used. (Such a wrist or heel strap should not create an electrical hazard for the wearer.)

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Service facilities

PC requirements

☐ Minimum requirement for Service software
- PC running Windows XP, Vista (32 bit) or 7 (32 bit)

☐ Access to Tech Support Website
Note: This will be provided at the discretion of the regional Technical Services Manager.

☐ Access to email with mailbox supporting attachments up to 7 MB

Service equipment

The range and accuracy of measuring equipment must meet the minimum requirements stated within the relevant service manual.
Equipment required:

☐ Pressure manometer

☐ Flow meter

☐ Flow regulation valve

☐ Digital thermometer with external probe

☐ Other product specific equipment as stated in the relevant service manual

Calibration control

☐ Measuring and testing devices used for servicing must be calibrated, have a calibration certificate, and calibration records maintained.

Inventory – units for servicing

Sufficient controls must be in place to ensure that there is no risk of mix up of faulty products, products undergoing repair or products that have completed the servicing requirement.
For example, upon receipt of a unit for servicing, the unit is to be labelled with the following information:

- Customer details
- Product details
- Problem details

Labelling should be clearly visible and securely fastened to the item it is identifying.

Note: A service request form can be used for this purpose, and attached to the front of the unit.

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Inventory – spare parts

☐ Sufficient controls must be in place to ensure that there is no risk of using faulty spare parts and obsolete spare parts.

☐ Parts with shelf life such as batteries must be identified and appropriately stored to avoid deterioration of shelf like during storage.

Spare parts must:

☐ Be ResMed approved parts

☐ Are not parts that have failed, show excessive wear, have been contaminated or are ineffective for their intended use.

Recording repair details and complaints handling

ResMed requires that all distributors maintain complete and accurate records of all customer's repaired goods and all other records as required by law for a minimum of five (5) years from the date of sale to the customer.
Distributors must display an established process for capturing and maintaining repair records. The minimum requirement for each repair record is:

- Unique repair identification
- Serial number
- Product code
- Brief description of problem
- Brief description of cause
- Repair action taken
- Parts used in repair
- Warranty status
- Customer details
- Date of service
- Name of individual servicing unit
- Test and calibration results

The database for capturing records:

☐ Oracle, OR

☐ Repairs Report Database, OR

☐ Other (Please provide details below)

Complaints handling

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- [ ] Service personnel must be familiar with ResMed's definition of a complaint and know the appropriate complaint handling procedures

Service personnel and training

- [ ] Service technician has suitable electrical and mechanical training to satisfy the requirements of the relevant regulatory authorities.

Training requirements

- [ ] The service technician must have completed training for any product platform they are servicing or reworking
- [ ] Personnel must demonstrate completion of training to ResMed's complaint handling and adverse event escalation procedures to ensure that ResMed is able to comply to its regulatory requirements for complaints handling
- [ ] Records of training undertaken by service centre personnel must be maintained
- [ ] Revision of training should be undertaken at a minimum of every 3 years and training records updated accordingly
- [ ] Where hand soldering is conducted, training to IPC standards is required

Competency criteria

Upon the completion of service training, the following competencies are expected:

- [ ] Familiar with ESD and environment control standards
- [ ] Understand the complaint and repair reporting requirements
- [ ] Familiar with cleaning and handling controls
- [ ] Familiar with the product
- [ ] Familiar with the different products in the series (where applicable)
- [ ] Recognise the major sub-assemblies in the product*
- [ ] Be able to properly perform the assembly/disassembly procedures for the product*
- [ ] Be able to correctly test and calibrate the product*
- [ ] Recognise and be familiar with the common failure modes in the product*
- [ ] Be familiar with the technical services website*

* indicates requirements for service technicians only